

# **FOOD AND DRUG ADMINISTRATION**

Center for Tobacco Products (CTP)

## **Tobacco Products Scientific Advisory Committee (TPSAC)**

**January 18-20, 2012**

1. Regarding the data from Sweden on smokeless tobacco products, discuss what, if any, extrapolations can be made:
  - a. To dissolvable tobacco use
  - b. From the impact of the use of traditional smokeless tobacco on health to the impact of the use of dissolvable tobacco on general health effects (including but not limited to oral, perinatal effects and cardiac events);
  - c. What limitations must be considered when making these extrapolations?
2. With respect to the peer reviewed articles on dissolvable tobacco products, please discuss:
  - a. What scientific findings are best supported by the literature?
  - b. What information gaps exist in the literature?
  - c. What additional research would inform potential regulatory action?
3. What post-marketing surveillance activities should be implemented to monitor poison events associated with dissolvable tobacco products?
4. Discuss whether dissolvable tobacco products increase overall initiation for the use of tobacco products and what further research would inform this question.
  - a. What evidence, if any, is there that dissolvable tobacco products encourage initiation of tobacco products?
  - b. What design features of dissolvable tobacco products encourage or discourage use by non-users?
  - c. In what way, if any, does initiation of dissolvable tobacco products encourage eventual graduation to the use of other forms of tobacco?
5. Discuss youth perception of dissolvable tobacco products and what further research would inform this question. What do children and adolescents think about dissolvable tobacco products and how might this affect use of the product?
  - a. What are the characteristics of dissolvable tobacco products that make them more or less appealing to children and adolescents, including users and non-users of tobacco products?
  - b. How do youth perceptions of dissolvable tobacco products compare to their perceptions of cigarettes and other smokeless tobacco products?
  - c. Which, if any, specific population groups are more likely to use dissolvable tobacco products?

6. Discuss adults' perception of dissolvable tobacco products and what further research would inform this question. What do adults think about dissolvable tobacco products and how might that affect use of the product?
  - a. What are the characteristics of dissolvable tobacco products that make them more or less appealing to adults, including users and non-users of tobacco products?
  - b. How do adults perceptions of dissolvable tobacco products compare to their perceptions of cigarettes and other smokeless tobacco products?
  - c. Which, if any, specific populations are more likely to use dissolvable tobacco products?
7. Discuss dual use of dissolvable tobacco products with other tobacco products and what further research would inform this question. To what extent are dissolvable tobacco products used in conjunction with other tobacco products by children, adolescents and adults?
  - a. How are dissolvable tobacco products used by children and adolescents in conjunction with other tobacco products (i.e., dual use)?
  - b. How are dissolvable tobacco products used by adults in conjunction with other tobacco products (i.e., dual use)?
  - c. What role, if any, does marketing play in promoting exclusive or dual use of dissolvable tobacco products?
8. Discuss potential abuse ability of dissolvable tobacco products and what further research would inform this question. What is the abuse liability of dissolvable tobacco products?
  - a. How do the nicotine levels and different rates of nicotine delivery impact dependence resulting from the use of dissolvable tobacco products?
  - b. In what ways, if any, do the design characteristics of dissolvable tobacco products or their packaging encourage or discourage use by targeted users?
  - c. What aspects, if any, of the design characteristics of dissolvable tobacco products encourage use by non-targeted populations and in ways other than as stated by the manufacturer?
  - d. In what ways, if any, could the abuse liability of dissolvable tobacco products be reduced?
  - e. How does the abuse liability of dissolvable tobacco products compare to that of other tobacco products?
9. Discuss cessation rates as related to dissolvable tobacco products and what further research would inform this question. How are the tobacco cessation rates associated with use of dissolvable tobacco products related to the tobacco cessation rates for users of other tobacco products?
  - a. How does cessation differ among adolescents and adults with dissolvable tobacco products compared with other tobacco products?
  - b. What evidence, if any, suggests that children, adolescents and adults delay tobacco cessation by using dissolvable tobacco products?
  - c. What evidence, if any, suggests that dissolvable tobacco products alter tobacco cessation for users of other types of tobacco products (i.e., do users switch to dissolvable tobacco products rather than quit)?

10. Discuss the morbidity and mortality associated with the use of dissolvable tobacco products and what further research would inform this question.
  - a. How does the morbidity and mortality associated with use of dissolvable tobacco products differ compared to that associated with use of other tobacco products?
11. Discuss the marketing strategies currently used to promote dissolvable tobacco products and what further research would inform this question.
  - d. Who is the target audience of dissolvable tobacco product marketing?
  - e. What are the primary messages used in dissolvable tobacco product marketing?
  - f. How does the marketing of dissolvable tobacco products affect consumer perceptions of the product?
  - g. How is the marketing of dissolvable tobacco products similar to and different from other tobacco products?
12. Discuss the public health impact, if any, and what further research would inform questions relating to:
  - a. Risk of accidental ingestion of dissolvable tobacco products
  - b. Safety of package design of dissolvable tobacco products
  - c. Topography of use of dissolvable tobacco products
  - d. Youth perception of dissolvable tobacco products
  - e. Impact of the use of dissolvable tobacco on cardiovascular health
  - f. How knowledge of the impact of the use of chronic nicotine replacement therapy on health could inform the use of dissolvable tobacco products.